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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 10/587,082 | 07/21/2006 | Anton Mayr | 09914.0006 | 6952 |
| 22852 7590 01/10/2008 FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
| | | | EXAMINER BLUMEL, BENJAMIN P | |
| | | | ART UNIT 1648 | PAPER NUMBER |
| | | | MAIL DATE 01/10/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/587,082 | Applicant(s) MAYR ET AL. | |
| | Examiner Benjamin P. Blumel | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-69 is/are pending in the application.
- 4a) Of the above claim(s) 56-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of invention I in the reply filed on October 24, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, upon further consideration, the species election has been withdrawn.

Claims 56-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species and inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 24, 2007.

Claims 46-55 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on July 21, 2006 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 46 is rejected under 35 U.S.C. 102(b) as being anticipated by McCabe et al.

(Vaccine, 2002).

The claimed invention is drawn to a method for producing a monoparamunity inducer, comprising:

- (a) isolating a myxoma virus from infected tissue of a rabbit;
- (b) adapting the virus to a permissive cell system; and
- (c) passaging the adapted virus to generate an attenuated myxoma virus that induces monoparamunity.

McCabe et al. teach the isolation of a myxoma virus from rabbits and its subsequent adaption/attenuation by serial passaging in Rabbit Kidney cells (RK-13). Therefore, the claimed invention is anticipated.

Claims 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al. (Journal of Infectious Diseases, 1964).

The claimed invention is drawn to a method for producing a monoparamunity inducer, comprising:

- (a) isolating a myxoma virus from infected tissue of a rabbit;
- (b) adapting the virus to a chorioallantoic membrane of incubated chicken eggs
; and
- (c) passaging the adapted virus to generate an attenuated myxoma virus that induces monoparamunity.

Saito et al. teach the attenuation of a two myxoma virus strains by adapting the viral isolates through serial passaging in the chorioallantoic membrane of White Leghorn Hen eggs followed by serial passaging in rabbit kidney cells. Therefore, the claimed invention is anticipated.

Claims 46 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Perera et al. (US 2006/0147419 A1).

The claimed invention is drawn to a method for producing a monoparamunity inducer, comprising:

- (a) isolating a myxoma virus from infected tissue of a rabbit;
- (b) adapting the virus to a chorioallantoic membrane of incubated chicken eggs
- ; and
- (c) passaging the adapted virus to generate an attenuated myxoma virus that induces monoparamunity.

Perera et al. teach a method of obtaining attenuated poxviruses through serial passaging in chicken eggs or chicken endothelial fibroblasts. Of these poxviruses, Perera et al. identifies myxoma virus as a target of attenuation through serial passaging. The claimed invention is therefore anticipated.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayr (US 2003/0013190 A1) in view of Saito et al.

The claimed invention is drawn to a method for producing a monoparamunity inducer, comprising:

- (a) isolating a myxoma virus from infected tissue of a rabbit;
- (b) adapting the virus to a chorioallantoic membrane of incubated chicken eggs
- ; and
- (c) passaging the adapted virus in Vero cells with at least 80 to at least 150 serial passages to generate an attenuated myxoma virus that induces monoparamunity.

Mayr teaches the further attenuation of MVA which was previously adapted by culturing in chicken eggs at the chorioallantoic membrane and initially attenuated with numerous passages

in CEFs. Mayr achieves this further attenuation by passaging MVA in Vero cells 100 times and 200 times thus producing Vero-MVA-100 and Vero-MVA-200, respectively. However, Mayr doesn't teach the attenuation of *myxoma virus*.

The teachings of Saito et al. are discussed above.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Mayr in order to attenuate *Myxoma virus* in vero cells. One would have been motivated to do so, given the suggestion by Mayr that the method be used to attenuate MVA (a member of the same family as *Myxoma virus*). There would have been a reasonable expectation of success, given the knowledge that *Myxoma virus* can be attenuated following adaptation in chicken eggs and serial passage in RK cells, as taught by Saito et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the AVIVER cells are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. §

112, first paragraph, may be satisfied by a deposit of the AVIVER cells. See 37 CFR 1.802. One cannot practice the claimed invention without these cells which support myxoma virus replication. One cannot determine whether an attenuated myxoma virus has the necessary characteristics without access to these cells. Therefore, access to the AVIVER cells is required to practice the invention. The specification does not provide a repeatable method for attenuating myxoma virus without access to the AVIVER cells and it does not appear to be readily available material.

Deposit of the AVIVER cells in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 46 recites, "...an attenuated myxomavirus that induces monaparamunity."

However it is unclear what monaparamunity is since no definition is provided in the specification.

Claim Objections

Claim 46 is objected to because of the following informalities: it appears that “monoparamunity” has been mis-spelled as “monaparamunity”. Appropriate correction is required.

Summary

No claims are allowed. Claims 52-55 are free of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "Benjamin P. Blumel", written over the printed name.

/Benjamin P. Blumel/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner
Art Unit 1648